Jason B. Lattimore
LATHAM & WATKINS LLP
One Newark Center, 16th Floor
Newark, NJ 07101-3174
Telephone: +1 973.639.1234
Facsimile: +1 973.639.7298

Attorneys for Defendant Orchid Chemicals & Pharmaceuticals Ltd.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS LTD., MERZ PHARMA GMBH & CO. KGAA, and MERZ PHARMACEUTICAL GMBH, Plaintiff, v. ORCHID CHEMICALS & PHARMACEUTICALS LTD., Defendants.	Civil Action No. 3:09-cv-05105 (MLC)(DEA) *ELECTRONICALLY FILED* **ANSWER OF ORCHID CHEMICALS & PHARMACEUTICALS LTD.** **COUNTERCLAIMS OF ORCHID CHEMICALS & PHARMACEUTICALS LTD.**

STATEMENT PURSUANT TO L.CIV.R. 10.1

Defendant Orchid Chemicals & Pharmaceuticals Ltd. is a company organized and existing under the laws of India with its principal place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India.

ANSWER OF ORCHID CHEMICALS & PHARMACEUTICALS LTD.

Defendant Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid") hereby answers the Complaint of Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, "Plaintiffs") and counterclaim as follows. Orchid hereby denies all allegations not otherwise admitted or denied.

RESPONSE TO PARTIES[1]

1. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 of the Complaint and, therefore, denies the allegations of paragraph 1 on that basis.

2. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint and, therefore, denies the allegations of paragraph 2 on that basis.

3. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint and, therefore, denies the allegations of paragraph 3 on that basis.

4. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint and, therefore, denies the allegations of paragraph 4 on that basis.

5. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 5 of the Complaint and, therefore, denies the allegations of paragraph 5 on that basis.

[1] To facilitate the Court's comparison of the allegations in the Complaint and defendants' responses thereto, Orchid has incorporated modified Headings that appear in the Complaint. Orchid does not necessarily agree with characterizations in such Headings and does not waive any rights to object to such characterizations or their implications.

6. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 6 of the Complaint and, therefore, denies the allegations of paragraph 6 on that basis.

7. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 7 of the Complaint and, therefore, denies the allegations of paragraph 7 on that basis.

8. Orchid denies the allegations of paragraph 8 of the Complaint, except admits that Orchid Pharmaceuticals Inc. is a Delaware corporation and a wholly-owned subsidiary of Orchid Chemicals & Pharmaceuticals Ltd.

9. Orchid denies the allegations of paragraph 9 of the Complaint, except admits that Orchid Chemicals & Pharmaceuticals Ltd. is an Indian corporation having a place of business at Orchid Towers, 313 Valluvar Kottam High Road, Nungambakkam, Chennai, Tamil Nadu 600 034 India and a place of business at Plot No. B3-B6 & B11-B14, SIPCOT Industrial Park, Irungattukottai, Sriperumbudur, Kancheepuram District, 602 105 India, and that Orchid Chemicals & Pharmaceuticals Ltd. manufactures generic drug products.

10. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10 of the Complaint and, therefore, denies the allegations of paragraph 10 on that basis.

11. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11 of the Complaint and, therefore, denies the allegations of paragraph 11 on that basis.

12. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12 of the Complaint and, therefore, denies the allegations of paragraph 12 on that basis.

13. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 of the Complaint and, therefore, denies the allegations of paragraph 13 on that basis.

RESPONSE TO NATURE OF THE ACTION

14. In responding to paragraph 14, Orchid admits that the Complaint purports to state claims for infringement of United States Patent No. 5,061,703 ("the '703 patent"), which are based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*., but Orchid denies any liability or wrongdoing whatsoever.

RESPONSE TO JURISDICTION AND VENUE

15. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 15 of the Complaint, except admits that the District of New Jersey has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), but Orchid denies any liability or wrongdoing whatsoever.

16. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 16 of the Complaint, except admits that for purposes of this action only that it is subject to personal jurisdiction in the District of New Jersey.

17. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17 of the Complaint and, therefore, denies the allegations of paragraph 17 on that basis.

18. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18 of the Complaint and, therefore, denies the allegations of paragraph 18 on that basis.

19. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19 of the Complaint and, therefore, denies the allegations of paragraph 19 on that basis.

20. Orchid denies the allegations in paragraph 20 of the Complaint.

21. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 21 of the Complaint, except admits that for purposes of this action only that it is subject to personal jurisdiction in the District of New Jersey.

22. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 of the Complaint and, therefore, denies the allegations of paragraph 22 on that basis.

23. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 of the Complaint and, therefore, denies the allegations of paragraph 23 on that basis.

24. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24 of the Complaint and, therefore, denies the allegations of paragraph 24 on that basis.

25. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25 of the Complaint and, therefore, denies the allegations of paragraph 25 on that basis.

26. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 26 of the Complaint, except admits that for purposes of this action only that venue is proper in the District of New Jersey.

RESPONSE TO THE PATENT-IN-SUIT

27. Orchid admits that United States Patent No. 5,061,703, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," states on its face that it was issued October 29, 1991 by the United States Patent and Trademark Office. Orchid denies that the '703 patent was "duly and legally issued" by the United States Patent and Trademark Office. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 27 of the Complaint and, therefore, denies them on that basis.

28. Orchid admits that the '703 patent is listed in the Orange Book for Namenda®, but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 of the Complaint and, therefore, denies them on that basis.

29. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29 of the Complaint and, therefore, denies the allegations of paragraph 29 on that basis.

30. Orchid admits that an ex parte reexamination certificate for the '703 patent indicates on its face that it was issued by PTO on November 7, 2006. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 30 of the Complaint and, therefore, denies the remaining allegations of paragraph 30 on that basis.

RESPONSE TO ALLEGED ACTS GIVING RISE TO THIS ACTION

Count I – Alleged Infringement of the '703 Patent by Defendant Cobalt

31. – 36. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 31-36 of the Complaint and, therefore, denies the allegations of paragraphs 31-36 on that basis.

Count II – Alleged Infringement of the '703 Patent by Defendants Lupin and Lupin Pharma

37. – 44. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 37-44 of the Complaint and, therefore, denies the allegations of paragraphs 37-44 on that basis.

Count III – Alleged Infringement of the '703 Patent by Defendant Orchid

45. Orchid admits that it submitted ANDA No. 90-044 to FDA seeking approval to market a 5 milligram and 10 milligram memantine hydrochloride tablet product prior to the expiration of the '703 patent and otherwise denies the allegations of paragraph 45 of the Complaint.

46. Orchid admits that, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, it indicated in ANDA No. 90-044 its contention that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Orchid Generic Products and that Plaintiffs received written notification of ANDA

No. 90-044 and its § 505(j)(2)(A)(vii)(IV) certification on or about December 10, 2007, but otherwise denies the allegations of paragraph 17 of the Complaint.

47. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 47 of the Complaint.

48. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 48 of the Complaint.

49. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 49 of the Complaint.

50. Orchid denies the allegations of paragraph 50 of the Complaint, except admits that Orchid Chemicals & Pharmaceuticals Ltd. was aware of the '703 patent prior to the filing date of ANDA No. 90-044.

51. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 51 of the Complaint.

52. Orchid denies each and every allegation and/or legal conclusion contained in paragraph 52 of the Complaint.

Count IV – Alleged Infringement of the '703 Patent by Defendant Teva

53. – 58. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 53-58 of the Complaint and, therefore, denies the allegations of paragraphs 53-58 on that basis.

Count V – Alleged Infringement of the '703 Patent by Defendant Upsher-Smith

59. – 64. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 59-64 of the Complaint and, therefore, denies the allegations of paragraphs 59-64 on that basis.

Count VI – Alleged Infringement of the '703 Patent by Defendants Wockhardt and Wockhardt USA

65. – 72. Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 65-72 of the Complaint and, therefore, denies the allegations of paragraphs 65-72 on that basis.

RESPONSE TO PRAYER FOR RELIEF

73. Orchid repeats and realleges its responses to the allegations in paragraphs 1 through 72 of the Complaint as though fully set forth herein. The "WHEREFORE" paragraphs following paragraph 72 of the Complaint state Plaintiffs' prayer for relief for which no response is required. To the extent a response is required, Orchid denies the allegations set forth in the "WHEREFORE" paragraphs and denies that Plaintiffs are entitled to any of the relief requested therein, or to any relief whatsoever.

DEFENSES

First Defense

(Non-infringement)

74. Orchid repeats and realleges its responses to the allegations in paragraphs 1 through 73 of the Complaint as though fully set forth herein.

75. Orchid does not infringe, has not infringed, and will not infringe (directly, indirectly, contributorily or by inducement) any valid and enforceable claim of the '703 patent.

Second Defense

(Invalidity)

76. Orchid repeats and realleges its responses to the allegations in paragraphs 1 through 75 of the Complaint as though fully set forth herein.

77. Upon information and belief, each and every claim of the '703 patent is invalid and void for failure to meet the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, 132, and 305.

Third Defense

(Invalidity of PTE)

78. Orchid repeats and realleges its responses to the allegations in paragraphs 1 through 77 of the Complaint as though fully set forth herein.

79. Upon information and belief, the patent term extension for the '703 patent is invalid due to a material failure to comply with the requirements of 35 U.S.C. § 156.

COUNTERCLAIMS

Defendant/Counterclaimant Orchid Chemicals & Pharmaceuticals Ltd. ("Counterclaimant") brings the following Counterclaims against Plaintiffs/Counterdefendants Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively "Counterdefendants").

The Parties

1. Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid") is a company organized and existing under the laws of India with its principal place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India.

2. Upon information and belief, Counterdefendant Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

3. Upon information and belief, Counterdefendant Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

4. Upon information and belief, Counterdefendant Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany.

5. Upon information and belief, Counterdefendant Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as "Merz").

6. Upon information and belief, Merz is the owner of United States Patent No. 5,061,703 ("the '703 patent"), titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," a copy of which is attached to Counterdefendants' Complaint as Exhibit A.

7. Upon information and belief, Forest asserts that it is the exclusive licensee of the '703 patent in the United States and Forest holds New Drug Application ("NDA") No. 21-487 for Namenda brand memantine hydrochloride tablets.

Nature of the Action

8. This is an action for a declaration of patent noninfringement, invalidity and patent de-listing arising under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction And Venue

9. This Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. Upon information and belief, this Court has jurisdiction over Counterdefendants.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(d), as well as Counterdefendants' motion to transfer this case to this judicial district.

12. Counterdefendants have created an actual controversy between themselves and Orchid through listing of the '703 patent in the Orange Book, as well as by virtue of its allegations that Orchid's submission of ANDA No. 90-044 to FDA constituted an act of infringement under 35 U.S.C. § 271(e) with regard to one or more claims of the '703 patent.

The Patents and Related Drug Product

13. Pursuant to 21 U.S.C. § 355(j), the Federal Food, Drug and Cosmetic Act ("FDCA") authorizes a generic drug company to file an ANDA with FDA for approval of a generic drug product that has the same active ingredient as, and is bioequivalent to, a drug product that FDA has already approved pursuant to an NDA.

14. Pursuant to 21 U.S.C. § 355(b), the FDCA requires NDA holders to submit to FDA the patent numbers and expiration dates of any patent that claims the drug or a method of using the drug for which an NDA is filed. FDA then lists those patents in The Orange Book.

15. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), if a generic drug company seeks approval to market a generic drug product prior to the expiration of a patent listed in the Orange Book, the generic drug company is required by law to include a certification in its ANDA that the patent is invalid, unenforceable, or will not be infringed by the generic drug product ("Paragraph IV Certification").

16. Pursuant to 21 U.S.C. § 355(j)(2)(B), if the generic drug company includes a Paragraph IV Certification in its ANDA, the generic drug company must send the NDA holder and the patent owner notice of that certification, including a detailed statement of the factual and legal basis for the generic drug company's opinion that the patent is invalid, unenforceable or will not be infringed ("Notice Letter").

17. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), if a suit for patent infringement is brought within 45 days of receiving the Notice Letter, FDA generally may not grant final approval for the generic drug company's ANDA for 30 months or until resolution of the patent infringement action.

18. On information and belief, Forest is the holder of NDA No. 21-487 for memantine hydrochloride tablets. On information and belief, the trade name of Forest's memantine hydrochloride tablet product is Namenda.

19. On information and belief, Forest requested that FDA list the '703 patent in The Orange Book for Namenda, NDA No. 21-487.

20. Orchid filed ANDA No. 90-044 with FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the memantine hydrochloride tablet product described in its ANDA prior to the expiration of the '703 patent. Orchid included in ANDA No. 90-044 a Paragraph IV Certification stating that, in the opinion of Orchid, and to the best of its knowledge, the '703 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the memantine hydrochloride tablet product described in its ANDA.

21. By letter dated December 7, 2007, Orchid sent Counterdefendants a Notice Letter that included a detailed statement of the factual and legal basis for Orchid 's opinion that its memantine ANDA product would not infringe any valid and enforceable claim of the '703 patent. Pursuant to 21 U.S.C. § 355(j)(5)(C), the Notice Letter was accompanied by an Offer of Confidential Access to ANDA No. 90-044. On or about December 10, 2007, Counterdefendants received the Notice Letter.

22. On or about January 10, 2008, Counterdefendants filed a Complaint in the District of Delaware against Orchid Chemicals & Pharmaceuticals Ltd., and Orchid Pharmaceuticals Inc. alleging infringement of the '703 patent. Counterdefendants asserted in their Complaint that the filing of ANDA No. 90-044 was an act of infringement of the '703 patent under 35 U.S.C. § 271(e)(2). Counterdefendants also asserted in their Complaint that the commercial manufacture, use, offer for sale, sale, or importation of the product described in ANDA No. 90-044 would infringe one or more claims of the '703 patent under 35 U.S.C. § 271.

23. Counterdefendants' assertion against Orchid of claims of infringement of the '703 patent after being advised by Orchid in its Notice Letter that there is no basis for those claims renders the Counterclaimant's case exceptional within the meaning of 35 U.S.C. § 285.

24. Orchid has no adequate remedy at law. The actions and assertions made by Counterdefendants with respect to the '703 patent have caused and will continue to cause irreparable injury to the rights of Orchid.

First Counterclaim

(Declaratory Judgment Of Non-infringement)

25. Orchid repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

26. Orchid has not infringed any claim of the '703 patent by filing ANDA No. 90-044, and the commercial manufacture, use, importation, offer for sale and/or sale of the product described in ANDA No. 90-044 will not infringe any valid and enforceable claim of the '703 patent.

27. Because Orchid has not infringed and will not infringe any claim of the '703 patent, Plaintiffs and Counterdefendants are not entitled to damages or any other relief from or against Orchid.

Second Counterclaim

(Declaratory Judgment Of Invalidity)

28. Orchid repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

29. Each and every claim of the '703 patent is invalid and void for failure to meet the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, 132, and 305.

Third Counterclaim

(Order To Delist The '703 Patent from The Orange Book)

30. Orchid repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

31. Forest's NDA No. 21-487 for Namenda® brand memantine hydrochloride tablets is approved by the Food and Drug Administration ("FDA") for the treatment of moderate to severe dementia of the Alzheimer's type.

32. The '703 patent does not claim the use of memantine in a method for the treatment of moderate to severe dementia of the Alzheimer's type and, therefore, does not claim an approved method of using memantine hydrochloride.

33. Pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb), Orchid is entitled to an Order requiring Counterdefendants to remove the '703 patent from the Orange Book for NDA No. 21-487.

PRAYER FOR RELIEF

WHEREFORE, Orchid Chemicals & Pharmaceuticals Ltd. respectfully requests this Court enter a Judgment and Order:

A. dismissing the Complaint, and each and every Claim for Relief contained therein, with prejudice;

B. an Order requiring Counterdefendants to remove the '703 patent from the Orange Book for NDA No. 21-487;

C. declaring that no valid and enforceable claim of United States Patent No. 5,061,703 has been or would be infringed (either directly, indirectly, contributorily or by inducement) by Orchid;

D. declaring the claims of United States Patent No. 5,061,703 invalid;

E. declaring this case exceptional pursuant to 35 U.S.C. § 285 and awarding Orchid its attorneys' fees, costs and expenses; and

F. granting such other and further relief as this Court may deem just and proper.

Dated: October 14, 2009

s/ Jason B. Lattimore

JASON B. LATTIMORE
LATHAM & WATKINS LLP
One Newark Center, 16th Floor
Newark, NJ 07101-3174
Telephone: (973) 639-1234
Facsimile: (973) 639-7298

OF COUNSEL

TERRENCE J. CONNOLLY (*pro hac vice*)
LATHAM & WATKINS LLP
885 Third Avenue, Suite 1000
New York, NY 10022-4834
Tel: (212) 906-1200
terrence.connolly@lw.com

KENNETH G. SCHULER (*pro hac vice*)

LATHAM & WATKINS LLP
Sears Tower, Suite 5800
233 South Wacker Drive
Chicago, IL 60606
Tel: (312) 876-7700
kenneth.schuler@lw.com

DARRYL H. STEENSMA (*pro hac vice*)
LATHAM & WATKINS LLP
12636 High Bluff Drive, Suite 400
San Diego, CA 92130
Tel: (858) 523.5400
darryl.steensma@lw.com

Attorneys for defendant Orchid Chemicals & Pharmaceuticals, Ltd.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that to the best of my knowledge the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/ Jason B. Lattimore
Jason B. Lattimore

Dated: October 14, 2009